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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/882,274 | 06/15/2001 | Alex B. Burgin JR. | P-RD 4806 | 7878 |
| 23601 | 7590 | 11/03/2003 | EXAMINER | |
| CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122 | | | LU, FRANK WEI MIN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1634 | |

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|---------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/882,274 | BURGIN ET AL. | |
| | Examiner | Art Unit | |
| | Frank W Lu | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on July 23, 2003 has been entered. The claims pending in this application are claims 1-16. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on July 23, 2003.

Claim Objections

2. Claim 15 is objected to because of the following informality: " at one or more terminal ends" should be "at its one or more ends".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4 and 6-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 is rejected as vague and indefinite. Since the claim is directed to a method of non-enzymatic ligation of a nucleic acid and there is no ligation step in the content of the claim, the goal of the method can not be reached. Applicant is required to add a ligation step into the claim in order to overcome the rejection. Please clarify.

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6. Claim 5 is rejected as vague and indefinite in view of preamble of the claim and step (b) of the claim. Since the claim is directed to a method of generating a polynucleotide product and last step of the claim (step (b) is a transducing step, the goal of the method and the last method step does not correspond each other. Please clarify.

7. Claim 6 is rejected as vague and indefinite. Although step (a) of the claim is directed to produce a polynucleotide-3' phosphorothiolate, there is no step for forming polynucleotide-3' phosphorothiolate in step (a) of the claim. The phrase "to produce polynucleotide-3' phosphorothiolate" is not considered as a step for generating a vector and is considered as a purpose. Although the claim is directed to non-enzymatic ligation of a nucleic acid, there is no non-enzymatic ligation step in the claim. Please clarify.

8. Claim 8 is rejected as vague and indefinite. Although the claim is directed to a method of molecular cloning, there is no step for generating a vector. The phrase "to generate a vector" is not considered as a step for generating a vector and is considered as a purpose. Furthermore, it is unclear that "an insert polynucleotide" in a vector is different from "an insert" in line 2 of the claim or not. Please clarify.

9. Claim 9 is rejected as vague and indefinite in view of the phrase "said vector comprising an insert polynucleotide" because it is unclear that "an insert polynucleotide" in claim 9 is the same as "an insert polynucleotide" in claim 8. If "an insert polynucleotide" in claim 9 is the same as "an insert polynucleotide" in claim 8, applicant is required to change "said vector comprising an insert polynucleotide" to "said vector comprising the insert polynucleotide" in order to overcome the rejection. Please clarify.

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10. Claim 11 is rejected as vague and indefinite. Although the claim is directed to a method of molecular cloning, there is no cloning step in the content of the claim. Although step (a) of the claim is directed to produce a polynucleotide-3' phosphorothiolate, there is no step for forming polynucleotide-3' phosphorothiolate in step (a) of the claim. Although step (b) of the claim is directed to generate a vector, there is no step for generating a vector. The phrase "to generate a vector" is not considered as a step for generating a vector and is considered as a purpose.

Furthermore, it is unclear that "an insert polynucleotide" in a vector is different from "an insert" in line 7 of the claim or not. Please clarify.

11. Claim 12 is rejected as vague and indefinite. Although the claim is directed to a method of molecular cloning, there is no cloning step in the content of the claim. Although the claim is directed to generate a vector, there is no step for generating a vector. The phrase "to generate a vector" is not considered as a step for generating a vector and is considered as a purpose. It is also unclear whether a vector comprising said acceptor polynucleotide has said polynucleotide-3' phosphorothiolate or not. Please clarify.

12. Claim 15 is rejected as vague and indefinite. Since claims 12 and 15 do not specify that said vector is linear, it is possible that said vector is circular. If said vector is circular, the vector is no terminal end which is opposite to claim 15. Therefore, in this situation, the phrase "one or more terminal ends" in the claim lacks insufficient antecedent basis. Please clarify.

13. Claim 16 is rejected as vague and indefinite. Although step (a) is directed to generate a polynucleotide-3' phosphorothiolate, there is no step for forming polynucleotide-3' phosphorothiolate. The phrase "to produce polynucleotide-3' phosphorothiolate" is not

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considered as a step for generating a vector and is considered as a purpose. Furthermore, although step (b) is directed to generate a vector, there is no step for generating a vector. The phrase "to generate a vector" is not considered as a step for generating a vector and is considered as a purpose. It is also unclear whether a vector comprising said acceptor polynucleotide has said polynucleotide-3' phosphorothiolate or not. Please clarify.

Conclusion

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Frank Lu', is positioned above the printed name.

Frank Lu

PSA

October 29, 2003